

REMARKS

The pending Office Action addresses and rejects claims 1-9, 11-17, 20, and 21.
Reconsideration and allowance is respectfully requested in view of the following remarks.

Rejection Pursuant to 35 U.S.C. §102

U.S. Patent 5,906,632 of Bolton

The Examiner rejects claims 1-3, 6, 7, 11-14, 16, 17, 20, and 21 pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,906,632 of Bolton ("Bolton"). Applicants respectfully disagree.

Claims 1-9

Independent claim 1 recites a graft fixation device including a bioabsorbable radially expandable sheath and a bioabsorbable sheath expander. The sheath has a slot-free distal tip and at least two sidewalls that extend proximally therefrom and define a central lumen. Each sidewall has a substantially concave outer surface adapted to seat a graft member, and each sidewall is at least partially separated by a longitudinally oriented opening that extends from a proximal end along a substantial length of each sidewall and terminates at a position just proximal to the distal tip. The expander is adapted to be disposed in the central lumen of the sheath and is configured to deform the concave outer surface of the sidewalls toward a circular geometry.

Bolton fails to teach or even suggest an expandable sheath having a slot-free distal tip and at least two sidewalls that have a substantially concave outer surface and that are at least partially separated by a longitudinally oriented opening that extends from a proximal end and terminates at a position just proximal to the distal tip. Bolton discloses a deformable ring (20) and a screw (40) that is insertable through a cutout (220, 221) in the ring (20) to urge the ring (20) against an inner surface of a bone tunnel.

First, the Examiner asserts that tip/point 222 forms a slot-free distal tip. Point 222 on the ring (20) is not slot-free. To the contrary, point 222 includes an opening or slot (220) formed therein. Thus, Bolton fails to teach a slot-free distal tip, as required by claim 1.

The Examiner also asserts that the grooves (210) formed in the flat sections (212, 213) of the ring (20) are equivalent to the substantially concave outer surface of the sidewalls recited in

claim 1 of the present application. Claim 1, however, recites that the sidewalls extend proximally from the distal tip and define a central lumen. Thus, the plurality of grooves (210) formed in each flat section (212, 213) of Bolton's ring (20) result in a "sidewall" having an outer surface with a *series of ridges* – not a sidewall with a substantially concave outer surface, as required by claim 1.

Bolton also fails to disclose a longitudinally oriented opening that partially separates the sidewalls and extends from a proximal end and terminates just proximal to the distal tip. The Examiner asserts that the grooves (218) formed in the inner surfaces of the flat sections (212, 213) of the ring (20) are longitudinal openings having such a configuration. As an initial matter, a groove is not equivalent to an opening. Moreover, the grooves (218) extend from the distal cutout (220) to the proximal cutout (221). The Examiner argues that the grooves (218) terminate at a position proximal to the distal tip because they do not "open/terminate in distal tip 222." Assuming, for the sake of argument, that the Examiner is correct in asserting that the grooves (218) terminate at a position proximal to the distal end (222) of the ring (20), it must follow that the grooves (218) do not extend from the proximal end (223) of the ring (20) either. In other words, if terminating at the distal cutout (221) is terminating proximal to the distal tip of the ring (20), commencing at the proximal cutout (221) cannot be commencing at the proximal end of the ring (20), as the cutouts are positioned identically at the proximal and distal ends (223, 222), respectively.

Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Bolton and represent allowable subject matter.

Claims 11-17 and 20-21

Independent claim 11 recites a graft fixation kit including a bioabsorbable expandable sheath and a *plurality* of sheath expanders of *varying sizes*. In order to anticipate a claim, the prior art must teach each and every limitation of the claim. At col. 5, lines 59-61 and col. 6, lines 35-38, Bolton teaches choosing a deformable ring (20) and screw (40) "of the correct size corresponding to the bone tunnel 90 diameter." Bolton fails to disclose that expanders of varying sizes can be used with a *single* expandable sheath, as required by claim 11. Accordingly, independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Bolton and represent allowable subject matter.

U.S. Patent 6,887,271 of Justin et al.

The Examiner rejects claims 1-7 and 11-17 pursuant to 35 U.S.C. §102(e) as being anticipated by or, in the alternative, pursuant to 35 U.S.C. §103(a) as obvious in view of U.S. Patent 6,887,271 of Justin et al. ("Justin"). Applicants respectfully disagree.

Claims 1-9

Justin fails to teach or even suggest an expander that is adapted to deform a concave outer surface of a sheath toward a circular geometry. Justin discloses an expandable fixation member (20) that is adapted to receive an expansion plug (21). The Examiner asserts that the expansion plug (21, 52, 310) is capable of "flexing/deforming the concave outer surface of the sidewalls toward a circular geometry." However, the expansion plug (21, 52, 310) and fixation member (20) taught by Justin are configured such that the expansion plug (21, 52, 310) is only capable of forcing the bone engaging elements (11, 12) of the fixation member (20) and/or the graft material into contact with the bone tunnel – it is not capable of deforming the grooves (23) of the fixation member (20) toward a circular geometry, as required by claim 1. FIGS. 2 and 6 of Justin, which are reproduced below, clearly illustrate that the grooves (23) form a Y-shaped portion of the fixation member (20, 50). At col. 4, line 66 to col. 5, line 8 and col. 7, lines 46-54, Justin explains that the slots (124, 360, 370) are configured such that the bone engaging elements (11, 12) move in *opposed* directions to engage bone and lock the fixation member (20, 50) within the bone tunnel. This movement will thus not cause the Y-shaped portion to change shape. Moreover, since the Y-shaped portion is solid and does not include a lumen extending therethrough, it would not be possible for the expansion plug to force the sidewalls of the Y-shaped member into a circular geometry.

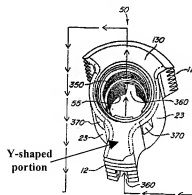
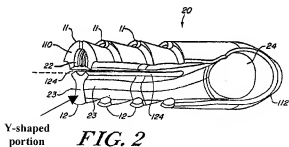


FIG. 6

Accordingly, independent claim 1, as well as claims 2-9 which depend directly or indirectly therefrom, distinguish over Justin and represent allowable subject matter.

Claims 11-17 and 20-21

Independent claim 11 recites a graft fixation kit including a bioabsorbable expandable sheath and a *plurality* of sheath expanders of *varying sizes*. In order to anticipate a claim, the prior art must teach each and every limitation of the claim. Justin fails to disclose a plurality of sheath expanders of varying sizes. Justin merely discloses one size expansion plug (21) and does not teach or even suggest that plugs of varying sizes can be used with a *single* fixation member (20), as required by claim 11. Accordingly, independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Justin and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. §103

WO 02/32345 of Jacobs, et al.

The Examiner rejects claims 1-4, 8, 9, 11-14, 20, and 21 pursuant to 35 U.S.C. §103(a) as being obvious over WO 02/32345 of Jacobs, et al. ("Jacobs"). The Examiner asserts that Jacobs teaches the claimed invention except for a "bioabsorbable" sheath expander. The Examiner argues that it would have been obvious "to have used a biodegradable expander with the invention of Jacobs, et al., since it has been held to be within the general skill of a worker in the art to select a know material." Applicants respectfully disagree.

Jacobs fails to teach or even suggest a sheath expander, much less an expander that is configured to deform a concave outer surface of a sheath toward a circular geometry, as required by claim 1. As acknowledged by the Examiner on pg. 6 of the Office Action, Jacobs does not explicitly disclose an "expander." The Examiner asserts that the device (190) shown in FIGS. 5A-5C and the insertion tool (184) shown in FIGS. 4C and 4D of Jacobs are equivalent to the expandable sheath and sheath expander recited in claim 1. Specially, the Examiner asserts that the insertion tool (184) is capable of deforming the external cavities (196) of the device (190) "in the direction of the circular geometry of the bone tunnel/bore." However, it would be impossible for the insertion tool (184) to deform any part of the device (190) because the insertion tool (184) must be configured to allow the spring arms (192, 194, 198, 200) of the device to *flex inward* as the device (190) is installed in a bone tunnel. As explained on pg. 12, lines 3-12 and shown in

FIG. 5C of Jacobs, “the various spring arms are pulled together when installed in a hole in the bone” to form an interference fit and secure the anchor device (190) within the bone tunnel. Thus, it would be impossible for the insertion tool (184) to act as an *expander*, as the device (190) must *contract* during installation.

Moreover, one having ordinary skill in the art would have no motivation to modify the insertion tool (184) of Jacobs to act as an expander. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP §2144). Not only is there is no advantage to modifying the anchor device (190) of Jacobs to include a sheath expander to *expand* the spring arms (192, 194, 198, 200) but such a modification is contrary to the teachings of Jacobs because, as explained above, the device (190) must *contract* during installation to secure the device (190) within the bone tunnel.

The Examiner further asserts that it would have been obvious “to have used a biodegradable expander with the invention of Jacobs.” However, one having ordinary skill in the art would have no motivation to make the insertion tool (184) of Jacobs out of a bioabsorbable material because the insertion tool (184) of Jacobs is not implanted. The insertion tool (184) is used merely to install the anchor device (190) and does not remain in the body after installation is complete. Moreover, bioabsorbable materials tend to be weak and are not generally suitable for insertion tools which require sufficient structural integrity.

Jacobs also fails to disclose a kit including a plurality of sheath expanders of varying sizes, as required by claim 11. Jacobs merely discloses one size pin (184) and does not teach or even suggest that expanders of varying sizes can be used with a *single* expandable sheath, as required by claim 11. Accordingly, independent claim 11, as well as claims 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Jacobs and represent allowable subject matter.

WO 02/32345 of Jacobs, et al. and U.S. Publication 2002/0072797 of Hays, et al.

The Examiner rejects claims 5-7 and 15-17 pursuant to 35 U.S.C. §103(a) as being obvious over Jacobs in view of U.S. Publication 2002/0072797 of Hays, et al. (“Hays”) now U.S. Patent 6,554,862. The Examiner asserts that Jacobs discloses the claimed invention except for the “stop member at a proximal end of the sheath” and “the expander as a tapered screw.” The

Examiner relies on Hays to teach these features arguing that it would have been obvious to combine the device of Jacobs with Hays to reach the claimed invention. Applicants respectfully disagree.

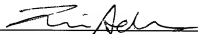
As explained above, Jacobs fails to teach or even suggest a sheath expander and there is no motivation to modify Jacobs to include such a feature. Hays does not provide the requisite motivation, as an *expander* is still contrary to the teachings of Jacob which require the device (190) to *contract* during installation. Accordingly, independent claims 1 and 11, as well as claims 2-9 and 12-17 and 20-21 which depend directly or indirectly therefrom, distinguish over Jacobs and Hays, taken alone or combined, and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

Date: April 23, 2007



Lisa Adams, Rég. No. 44,238
Attorney for Applicant(s)

Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210
Tel: (617)439-2550
Fax: (617)310-9550

1621497.1